

RECEIVED

APR 14 2003

TECH CENTER 1600/2900

HI  
CONT disease is characterized by decreased or insufficient production, or decreased or insufficient activity, of IL-10.

Please cancel claim 69.

REMARKS

1. We thank the Examiner for indicating that claims 18-22, 24-41, 63, 65-79 and 80-82 are allowable, and that 51-53, 59 and 61 would be allowable if rewritten in independent form. We also thank the Examiner for rejoining claims 57-59. However, we note that claim 69 does not appear to further limit rejected claim 49. We therefore have cancelled claim 69.

2. Claim 49 is rejected for indefiniteness because it recites "a method of treating a disease which is treatable by the recited substance, rather than reciting a specific disease." This is, in effect, a functional definition of the disease. MPEP §2173.05(g) acknowledges that "functional language does not, in and of itself, render a claim improper."

To determine whether a disease is included in claim 49, one need merely attempt to treat it with one of the cited substances. Naturally, if a disease is known or suspected to be one in which macrophase/T-lymphocyte-mediated immune reactions are considered pathogenically important (see Table 1), or for which an immune modulator with IL-10 life activity is considered to have therapeutic importance (see Table 2), it

is more likely to be so tested.

Claims of the type sought here have previously been granted. The following four patents recite "diseases treatable":

Takenaga, USP 5,723,121, claim 11 ("A method for treating hepatic diseases treatable with interferon which comprises administering to animals or humans an effective amount of the sugar-modified interferon claimed in claim 1.")

Schole-Loop, USP 5,760,230, claim 4 ("A method of treating diseases of the central nervous system wherein said diseases are treatable by blocking the apamin-sensitive potassium channels, which comprising administering an effective variant of a compound according to claim 1 to a host in need thereof.")

Inokuchi, USP 5,707,649, claim 8 ("A method for treating neuronal diseases treatable by elevating biosynthesis of endogenous glycosphingolipids... comprising administering ...a liposome composition comprising....")

Tamino, USP 5,192,799, claim 8 ("A method for treating psychoneurological diseases treatable with dopamine or serotonin antagonists in a patient in need thereof, comprising administering... the compound of claim 1....")

Another 22 patents recite a "disease treatable" (see Exhibit A, enclosed). Another 67 recited a "disease mediated"

(Exhibit B), and 25 recite "diseases mediated" (Exhibit C).

3. Claims 49 and 57 are rejected under §112 ¶2 on the ground that while the peptide of the present invention "can be used in treating inflammatory diseases, such as pancreatitis, ARDS-like syndrome, and arthritis," a person skilled in the art would not be able to predict that the compounds would be effective in treating other diseases.

In our opinion, no such predictability is required by patent law. Tables 1 and 2 enumerate many diseases that might be so treatable, and provide a rationale. It would not require undue experimentation to administer one of the recited compounds to a patient and observe whether one of the diseases is in fact responsive. In a similar manner, the responsiveness of diseases not on this list can be evaluated.

Claim 57 is directed to anticancer utility. New claim 85 recites psoriasis (page 4, line 34). We enclose, as Exhibit C, a copy of a poster relating to the involvement of cytokines in psoriasis and cancer.

New claim 83, based on page 1, line 11 and page 4, lines 18-28, recites that the disease is an "inflammatory disease." Claim 84 recites a "skin disease" (page 4, line 33); claim 86, an auto-immune disease (page 5, line 8), and claim 87, that the disease is characterized by decreased or insufficient production, or decreased or insufficient

activity, of IL-10 (page 7, lines 30-32).

We also respectfully direct the Examiner's attention to claims 57 (Table 2 diseases), 70 (disease involves pro-inflammatory activities), 71 (disease is one inhibited by IL-10), and 72 (disease is one caused or aggravated by IL-8, MCAF or IL-1). We understand that claims 70-72 are considered allowable.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant

By: 

Iver P. Cooper  
Reg. No. 28,005

Enclosures

- Exhibit A
- Exhibit B
- Exhibit C

624 Ninth Street, N.W.  
Washington, D.C. 20001  
Telephone: (202) 628-5197  
Facsimile: (202) 737-3528  
IPC:ma  
G:\ipc\n-q\Plou\GronhojLarsen2\PTO Amd 8Apr03.doc